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Delegations will find attached the final EU/Member States statements delivered at the above-mentioned WIPO meeting.

**WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources,
Traditional Knowledge and Folklore (Special Session)**

(Geneva, 4-8 September 2023)

Opening Statement

Chair,

1. On behalf of the European Union and its Member States, let me first thank you and your Vice-Chairs for your efforts to facilitate work in the IGC on Genetic Resources and Associated Traditional Knowledge. We would also like to thank the Secretariat for preparing this Special Session.
2. As regards potential outcomes of the negotiations, we would like to reiterate our view that any international instrument on GR and ATK, which have an impact on the patent system, should support a balanced and flexible approach. We have studied the text that is going to be the basis of the debates and we are happy to share our views on our preferred wording in the articles.
3. The EU and its Member States remain committed to engaging constructively during this Session, as well as in the Preparatory Committee meeting, and in the Diplomatic Conference that is ahead of us.

Thank you.

4. Genetic Resources

Preamble

This preamble can be supported by the EU, as it clearly states that the scope of the instrument is limited to patents.

As a general remark for the Preamble, as well as for the rest of the text, we understand that the basic proposal should use full text. GR should read genetic resources and ATK should read associated traditional knowledge.

Article 1

The EU agrees with the objectives of this instrument as reflected in Article 1.

There is a need to establish a definition of Traditional Knowledge Associated with Genetic Resources in this text. We consider his definition should be included in Article 2.

Article 2

We would like to reiterate our comment made in the previous article on the need to establish a definition of Traditional Knowledge Associated with Genetic Resources in this text. The EU stands ready to engage in discussions on developing a definition.

On the definition of “Country of origin of genetic resources”, the EU and its Member States support the definition proposed by the Chair, as it is identical with the definition in the CBD.

On the definition of “[Materially/Directly] based on”, we can support the outcome of the expert group meeting and the report -WIPO/GRTKF/IC/47/13, meaning that the trigger should be “materially and directly based on” which means that the Genetic Resource and/or Associated Traditional Knowledge must have been necessary for and material to the claimed invention and that the claimed invention must depend on the specific properties of the GRs and/or insights from the Associated Traditional Knowledge. This definition was elaborated and agreed upon by a group of experts reflecting different interests and balanced geographical representation and provides a balanced and adequate approach.

On the definition of “Genetic material”, “Genetic resources” and “In situ conditions”, the EU supports the definition proposed by the Chair, as it is identical with the definition in the CBD.

The EU proposes to delete the term “PCT”. This definition is not necessary because the respective term only appears in a footnote.

Article 3

Regarding Art. 3, the EU supports the use of the term “materially and directly based on” as the trigger for the disclosure requirement as proposed by the Virtual Expert Group and numerous delegations. We will make further comments regarding this term, when commenting on Article 2.

The EU also supports the addition of the wording proposed by the Expert Group on article 3.1. We consider that the added text, reading “the country of origin from which the GRs were obtained, or,”, read together with the definition of “country of origin”, makes it clear that the applicant should indicate the country which possesses the GRs in in situ conditions and from which the GRs were obtained. This could be important for cases where several countries possess the same GRs in in situ conditions, to clarify that the applicant should indicate only that one country from which the GRs were actually obtained.

As regards, 3.4, we consider that more discussion is needed as to the possible ways guidance could be given by the Offices. We are willing to actively engage in discussions to elaborate on this issue.

The EU supports the Chair’s text on Articles 3.3, 3.5 and 3.6.

Article 4

From our point of view, it should be clear that the exceptions and limitations limit the scope of the disclosure obligations, not expand them.

For this reason, we would add wording to this article: “In complying with the obligation set forth in Article 3, Contracting Parties may, in special cases, ~~adopt~~ *‘narrow the scope of the disclosure obligations by adopting’* justifiable exceptions and limitations, necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument or mutual supportiveness with other instruments.”

Article 5

The EU supports Article 5.

However, we would also like to emphasise that the Chair’s text only covers one of the two necessary aspects of non-retroactivity for this instrument. On top of non-retroactivity related to the time of the filing of a patent application, there should also be non-retroactivity related to the accession of a GR and ATK. As concerns the latter, only GRs and ATK which have been accessed after the entry in to force of the treaty should be covered by the disclosure requirement. This should be reflected in Article 5.

Article 6

The EU and its Member States attach great importance to a clear and precise framework on the sanctions. However, we would like to propose some amendments for the sake of clarification, similar to the ones that have already been proposed by other delegations:

We appreciate that 6.3 aims at a ceiling for sanctions for non-compliance with the disclosure obligations, that is, no revocation. We fully support that objective and the rationale explained in the Chair’s note to 6.3. Nevertheless, we are concerned that the current wording of 6.3 and 6.4 together does not safeguard such ceiling.

Also, the notion “fraudulent intent in regard to the disclosure requirement in Article 3 of this instrument” in 6.4 is not sufficiently clear since there is no common understanding what it is supposed to mean.

Therefore, we propose amendments to Articles 6.1 and 6.3 to set up a clear framework for sanctions.

We consider that Article 6.1 should set up the general basis for this article and determine that sanctions, in different kinds, can be adopted before and after the granting of the patent.

Therefore, we could propose the inclusion of the wording “both before and after the granting of a patent”. Article 6.1 would the read:

“Each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures, both before and after the granting of a patent, to address an applicant’s failure to provide the information required in Article 3.”

This way, the minimum standard would relate to both pre-grant and post-grant sanctions, whereas some other provisions would relate to either pre-grant only (6.2) or post-grant only (6.3). 6.4 would become superfluous, as Contracting Parties may provide for post-grant sanctions other than revocation in accordance with national law under 6.1 anyway. Given the problematic of the term “fraudulent intent”, and considering the proposed amendment in article 6.1, the EU considers that article 6.4 should be deleted in its entirety.

Additionally, we would support the deletion of the term “solely” on Article 6.3, as have been proposed by some delegations, such as the US.

The EU supports the proposal made by some delegations on Article 6.2 with regard to the inclusion of “within a prescribed period”. We consider that the inclusion of some wording mentioning that the rectification of the patent application in what refers to the disclosure of the information required in Article 3 should be allowed within a reasonable prescribed period of time.

The EU would like to seek clarification with regard to Article 6.5. For example, it is still unclear to us what we are referring to exactly with “adequate dispute mechanisms”? Who would be parties to a dispute settlement mechanism?

To ensure an independent (judicial) review on decisions relating to sanctions or remedies, the EU supports the proposal to include an additional article 6.6 relating to such an independent review on decisions.

Article 7

The EU supports the rationale behind Article 7 and its current drafting in the Chair's text.

Article 8

The EU supports the rationale behind Article 8 and its current drafting in the Chair's text. We remain flexible as to considering suggestions for amendments on this Article by other delegations.

Article 9

In general, the EU does not oppose the concept of a review clause. However, in our view, the four years to develop a review of the scope and content of this instrument seem too short.

This is because after the entry into force of the instrument, a number of time-consuming steps should be taken into account, namely:

- the time necessary for the incorporation of relevant provisions into the national patent laws;
- the time necessary, e.g., several years, to gather experience from at least a few applications; in four years, we may not even have had any applications on these issues yet;
- the procedure of examining patent applications takes time; it depends on the application, but we are not speaking of months, but years;
- issues on these matters could be taken to courts; obtaining final court decisions, that could be of interest to take into account for the review, also takes time.

All things considered, we believe four years is insufficient time to start a review that would be credible and conclusive. For this reason, we would propose to double that time frame and change the wording to "no later than eight years after the entry into force of this instrument".

The second concern related to Article 9 is the potential extension to other areas of IP and derivatives. According to the EU, the scope of this instrument should be limited to patents only, now and in the future. However, we could be flexible towards the Chair's text, for the sake of compromise.

The EU proposes to delete part of the article, leaving it open to different issues that may arise after the entry into force of the treaty.

Article 9 would then read:

The Contracting Parties commit to a review of the scope and contents of this instrument, addressing issues arising from new and emerging technologies that are relevant for the application of this instrument, no later than “eight” years after the entry into force of this instrument.
